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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Gil M. Vardi et al. Confirmation No.: 2222
Serial No.: 10/670,168 Examiner: Elizabeth Houston
Filed: September 25, 2003 Group Art Unit: 3731
For: DUAL GUIDEWIRE EXCHANGE CATHETER SYSTEM
Docket No.: 1001.2278101

PRE-APPEAL BRIEF REQUEST FOR REVIEW

<p>Mail Stop AF Assistant Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450</p>	<p>CERTIFICATE OF ELECTRONIC TRANSMISSION I hereby certify that this paper is being electronically transmitted to the United States Patent and Trademark Office on the date shown below.</p> <p><u>Kris Wilfrid</u> March 23, 2009 Kris Wilfrid Date</p>
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Applicant has received and carefully reviewed the Final Office Action mailed December 23, 2008 and the Advisory Action mailed March 6, 2009. Currently, claims 1-5, 8, 13-15, 19-23, and 28-31 remain pending, all of which stand finally rejected. Applicant hereby requests a pre-appeal conference and files this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

In paragraph 5 of the Final Office Action, claims 1-5, 8, 13-15, 19-23, and 28-31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (U.S. Patent No. 6,099,497). Turning to claim 1, which recites, in part, "said branch guidewire enclosure bonded to said channel only at said branch exit port". Nothing in Adams et al. appear to teach or suggest at least this limitation of claim 1. In fact, the Examiner appears to acknowledge that Adams fails to disclose that the branch guidewire enclosure is bonded to the channel only at said branch exit port or only at the three way bond (see paragraph 7 of the Final Office Action).

However, the Office Action continues to state that the mode of bonding the enclosure to the catheter is a matter of obvious design choice. Applicant must respectfully disagree. Design choices are discussed in the Manual of Patent Examining Procedure (MPEP) § 2144.04(VI)(C), but only insofar that they constitute a rearrangement of parts. MPEP § 2144.04(VI)(C) states:

In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (Claims to a hydraulic power press which read on the prior art except with regard to the position of the starting switch were held unpatentable because shifting the position of the starting switch would not have modified the operation of the device.); *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) (the particular placement of a contact in a conductivity measuring device was held to be an obvious matter of design choice). However, "The mere fact that a worker in the art could rearrange the

parts of the reference device to meet the terms of the claims on appeal is not by itself sufficient to support a finding of obviousness. The prior art must provide a motivation or reason for the worker in the art, without the benefit of appellant's specification, to make the necessary changes in the reference device "*Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351, 353 (Bd. Pat. App. & Inter. 1984).

(Emphasis added). From this passage, it appears that a mere rearrangement of parts is an obvious design choice unless the rearrangement would have modified the operation of the device. Further, it appears that "the mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims ... is not by itself sufficient to support a finding of obviousness", but that the prior art must provide a motivation or reason for the rearrangement.

Applicant must respectfully assert that "said branch guidewire enclosure bonded to said channel only at said branch exit port" modifies the operation of the device. For example, page 8, line 32 through page 9, line 4 of the application, provides some examples of how the claimed limitation may modify the operation of the device, such as the flexibility and stiffness characteristics of the catheter system. Page 8, line 32 through page 9, line 4 recites:

By distancing the balloon and stent from bond portion 24 (by around 10 cm or more), more flexibility in rotation of the system is provided, facilitating rotational alignment of side opening 34 of stent 32 with the ostium of the branch vessel. Furthermore, stiffness in the area of the stent is reduced by not having extra bond material present in the general region of the stent.

As is readily apparent from this passage, the limitation "said branch guidewire enclosure bonded to said channel only at said branch exit port" can provide for more flexibility in rotation of the system facilitating rotational alignment of side opening of stent with the ostium of the branch vessel. Additionally, the limitation "said branch guidewire enclosure bonded to said channel only at said branch exit port" may also provide for a reduced stiffness in the area of the stent. Accordingly, it is believed that the limitation "said branch guidewire enclosure bonded to said channel only at said branch exit port" modifies the operation of the claimed catheter system. Further, nothing in Adams et al. appear to provide any motivation or reason for modifying the device of Adams et al. to have "said branch guidewire enclosure bonded to said channel only at said branch exit port", as is required according to MPEP § 2144.04(VI)(C). Accordingly, Applicant must respectfully assert that "said branch guidewire enclosure bonded to said channel

only at said branch exit port” is not a mere design choice.

In the Advisory Action, the Examiner asserts that the Applicant’s specification does not provide criticality for this feature, but that the specification lists that feature of the distal shaft being attached only to the inflation tube at a specific point as one of many options for the location of the bond. While Applicant does not concede that “said branch guidewire enclosure bonded to said channel only at said branch exit port” is or is not critical, Applicant respectfully asserts that there appears to be no requirement, for this in the M.P.E.P. or C.F.R. Therefore, the Examiner’s assertion that “said branch guidewire enclosure bonded to said channel only at said branch exit port” is a mere design choice because it is not described as being critical in the Specification is clearly improper.

In the Advisory Action, the Examiner asserts that a person of ordinary skill has good reason to take the different types of attachments taught by Adams and pursue the known options within his or her technical grasp if it yields predictable results. Applicant must respectfully disagree. With regards to the rationale of “Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results” for establishing a *prima facie* case of obviousness, MPEP § 2143 (D) states:

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Then, Office personnel must articulate the following:

- (1) a finding that the prior art contained a “base” device (method, or product) upon which the claimed invention can be seen as an “improvement;”
- (2) a finding that the prior art contained a known technique that is applicable to the base device (method, or product);
- (3) a finding that one of ordinary skill in the art would have recognized that applying the known technique would have yielded predictable results and resulted in an improved system; and
- (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art. One of ordinary skill in the art would have been capable of applying this known technique to a known device (method, or product) that was ready for improvement and the results would have been predictable to one of ordinary skill in the art. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

Applicant respectfully asserts that "said branch guidewire enclosure bonded to said channel only at said branch exit port" is not a known technique contained in the prior art, namely Adams et al. In fact, the Examiner even acknowledged that Adams et al. fails to teach or suggest such a technique. Further, the Examiner has failed to provide any other documentary evidence showing such a feature. Thus, there is no finding that the prior art contained a known technique that is applicable to the base device (factual inquiry 2) and, therefore, there cannot be a finding that one of ordinary skill in the art would have recognized that applying the known technique would have yielded predictable results and resulted in an improved system (factual inquiry 3). Since these findings cannot be made, then the rationale of "Applying a Known Technique to a Known Device (Method, or Product) Ready for Improvement To Yield Predictable Results" cannot be used to support a conclusion that claim 1 is obvious to one of ordinary skill in the art.

In the Examiner is attempting to take Official Notice of "said branch guidewire enclosure bonded to said channel only at said branch exit port", Applicant reminds the Examiner that, with regards to the taking of Official Notice, M.P.E.P. 2144.03 (A) and (B) states:

Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known. As noted by the court in *In re Ahlert*, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970), the notice of facts beyond the record which may be taken by the examiner must be "capable of such instant and unquestionable demonstration as to defy dispute" (citing *In re Knapp Monarch Co.*, 296 F.2d 230, 132 USPQ 6 (CCPA 1961)).

If Official Notice Is Taken of a Fact, Unsupported by Documentary Evidence, the Technical Line of Reasoning Underlying a Decision To Take Such Notice Must Be Clear and Unmistakable

(Emphasis added). Applicant submits that the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known. Per MPEP 2144.03(C), Applicants respectfully traverse the taking of Official Notice and request the Examiner provide documentary evidence supporting the rejection in the next office action if the rejection is maintained.

The Examiner also asserts in the Advisory Action that the claims do not provide any

structure of the catheter system that is distinguishable from the prior art. Applicant must respectfully disagree and assert that "said branch guidewire enclosure bonded to said channel only at said branch exit port" is a structural limitation. For example, this limitation clearly defines the structure of the device, namely where the device includes bond material.

As the Examiner is well aware, § 2141 of the M.P.E.P. states:

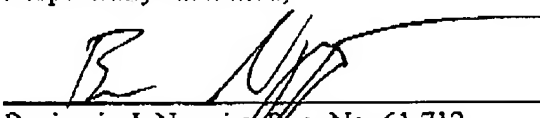
The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396.

(Emphasis added). The Examiner has clearly failed to establish any articulated reasoning with some rational underpinning to support that assertion that the claimed invention is obvious. Therefore, for at least these reasons, claim 1 is believed to be patentable over Adams et al. For similar reasons and others, independent claims 13 and 28 are believed to be patentable over Adams et al. Also, for similar reasons and others, claims 2-5, 8, 13-15, 19-23, and 29-31, which depend from one of claims 1, 13, and 28 and include additional limitations, are believed to be patentable over Adams et al.

Reconsideration and withdrawal of the rejection are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Dated: March 23, 2009


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